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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,796

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Hidenori Mikamiyama

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11/25/2009

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EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,796	Applicant(s) MIKAMIYAMA ET AL.	
	Examiner JEFFREY H. MURRAY	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 and 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 20, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to an amendment filed on July 10, 2009. There are twenty-seven claims pending and twelve claims under consideration. Claims 10-19 and 25-29 have been withdrawn. Claims 21 and 22 have been cancelled.

Withdrawn Rejections/Objections

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 contains the definition of "heteroaryl" but has since removed the term from the definition of Ar. The term is now superfluous and it is suggested that it be removed. In addition, a term has not been inserted for "heterocyclic" which still appears in the definition of R¹. Appropriate correction is required.

Examiner will hold the previous claim objection of non-elected subject matter in abeyance until such time as the claims are found allowable but for the claim objection.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 1-9, 20, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a 5-hydroxypyrimidin-4(3H)-one where R¹ can contain a 5- or 6-membered nitrogen containing heterocycle or a pharmaceutically acceptable salt thereof, does not reasonably provide enablement for where R¹ contains a heterocycle other than mentioned previously or the alcoholates,

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solvates or hydrates of the instantly claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants argue that the specification contains the teachings of the claimed compounds. However, only 5- and 6-membered nitrogen containing heterocycles are shown for R¹ in the synthesis of these compounds. It is well known that heterocyclic rings can play a major role in a chemical compound's structure with regards to hydrogen bonding, stereoselectivity, and steric hindrance. To simply claim that numerous other sized ring systems with varying amounts of heteroatoms would all produce a similar result without any support is in error. Applicants do not demonstrate any of these ring systems in the present examples. While examiner agrees, the present examples which are shown are enabled, this does not include any compounds where the R¹ is other than a 5- or 6-membered nitrogen-containing heterocyclic ring.

In regards to the alcoholates, solvates or hydrates of the instantly claimed compounds, applicants have not provided any method of making specific examples. Merely providing elemental analysis of a final compound is insufficient and confusing. The applicants have shown how to make 5-hydroxypyrimidin-4(3H)-ones. However, the synthetic scheme does not teach or demonstrate how an alcoholate, solvate or hydrate of the instantly claimed compounds is synthesized. Applicants claim to have made hydrates or alcoholates whereby the equivalent is 0.1 or 0.2. A showing by elemental analysis does not confirm the formation of an alcoholate, solvate or hydrate. Rather it merely shows the presence of a particular alcohol, solvent or water is present. In each

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instance, the applicants do not treat the final compound with an alcohol, solvent or water in order to obtain an alcoholate, solvate or hydrate, but rather the alcohol, solvent, or water was present somewhere throughout the reaction sequence, workup or purification and was merely left behind. It is well known in the chemical arts that compounds can remain "wet" from a solvent or water. Elemental analysis can not positively or negatively confirm whether a compound is indeed an alcoholate, solvate or hydrate, or if the compound simply has excess alcohol, solvent or water remaining. As was mentioned in the previous action, the scope of "alcoholate, solvate or hydrate" is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active *in vivo*. They cannot be predicted and therefore are not capable of being claimed if the applicant cannot properly enable a particular alcoholate, solvate or hydrate.

"Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds. Certain molecular shapes and features favor the formation of crystals without solvent; these compounds tend to be stabilized by efficient packing of molecules in the crystal lattice, whereas other crystal forms are more stable in the presence of water and/or solvents. There may be too many possibilities so that no computer programs are currently available for predicting the crystal structures of hydrates and solvates. Vippagunta et. al. Advanced Drug Delivery Reviews 48 (2001) 3-26.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re*

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Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for making these compounds as alcoholates, solvates or hydrates. Failure to make these compounds also relates directly to failure to use them in any methodological steps or procedures.

Conclusion

Claims 1-9, 20, 23 and 24 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner , Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**